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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,326	02/24/2004	Fredric J. Cohen	X-11057C	9685

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EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
05/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/785,326	COHEN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 145-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 145-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 2/18/2010, are acknowledged and entered. Claims 19 and 145-156 are pending and under examination.

Response to Arguments

Applicants' arguments have been fully considered and are persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The 35 U.S.C. 102(e) rejection of claims 19 and 145-152 as being anticipated by U.S. Patent No. 6,103,740 is **moot** in view of Applicant's amendments to claim 145. Said amendments are sufficient to overcome U.S. Patent No. 6,103,740 as prior art under 35 U.S.C. 102(e).

The 35 U.S.C. 103 rejection of claims 153-156 as being unpatentable over U.S. Patent No. 6,103,740 in view of U.S. Patent No. 5,393,763 is likewise rendered **moot** in light of Applicant's amendments to claim 145, which are sufficient to overcome U.S. Patent No. 6,103,740 as applicable prior art.

Claims 19 and 145-156 are newly rejected on the grounds of Non-Statutory Obviousness-Type Double Patenting over the claims of U.S. Patent Nos. 6,103,740, 6,008,232, 5,478,847, and 5,478,847. As evidenced by the Terminal Disclaimer filed 3/25/2005, the instant application is assigned to Eli Lilly and Company, which is the same assignee as the above referenced patents.

Regarding Obviousness-Type Double Patenting rejections set forth below, Applicants recitation of different biological effect of administration of 60 mg/day raloxifene hydrochloride to a post-menopausal woman as claimed in the cited patents does not distinguish the claimed method from the methods recited in the patent claims.

Practice of the methods recited in the cited patent claims will inherently result in reducing the likelihood of incurring or developing estrogen-dependent breast cancer in the treated patients because the same compound is being administered in the same amount to the same patients. In other words, Applicants recognition that administration of 60 mg/day of raloxifene hydrochloride to post-menopausal women as recited in the claims of the above cited patents reduces the incidence of estrogen-dependent breast cancer in those patients, in addition to lowering platelet counts ('740 patent), preventing headaches ('232 patent), lowering serum cholesterol ('168 patent), and/or inhibiting bone loss or bone resorption ('847 patent), does not distinguish the claimed methods from those recited in the above patent claims.

In light of the new ground of rejection set forth in the instant Office Action, this Office Action is **Non-Final**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19 and 145-152 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,103,740. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '740 patent claims comprises administration of raloxifene hydrochloride (claim 2) to a post-menopausal woman (claim 3) via oral administration of 60 mg/day (claim 4). Accordingly, the instantly claimed effects of such administration (*i.e.*, reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from the practice of the '740 patent method claims.

Claims 19 and 145-152 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,008,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '232 patent claims comprises administration of raloxifene hydrochloride (claim 2) to a post-menopausal woman (claim 3) via oral administration of 60 mg/day (claim 4). Accordingly, the instantly claimed effects of such administration (*i.e.*, reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from the practice of the '232 patent method claims.

Claims 19 and 145-152 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of U.S. Patent No. 5,610,168. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '168 patent claims comprises administration of raloxifene hydrochloride (claim 11) to a post-menopausal woman (claim 4) via administration of 60 mg/day (claim 6). Accordingly, the instantly claimed effects of such administration (*i.e.*, reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from the practice of the '168 patent method claims.

Regarding "administration" as recited in the '168 patent claims, the specification of the '168 is used as a dictionary to define such administration. In this regard, the inventors teach that the term of period of time of administration to a human will be at least 6 months, normally at

least one year, and preferably on a continual basis (col. 8, lines 24-30). The inventors further teach oral administration as recited in the instant claims (col. 7, lines 61-64).

Claims 19 and 145-156 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, and 12 of U.S. Patent No. 5,478,847. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active method step of the '847 patent claims comprises administration of raloxifene hydrochloride (claim 12) to a human diagnosed with osteoporosis (claim 2), to a post-menopausal woman (claim 3), via administration of 60 mg/day (claim 7), and wherein the raloxifene is administered prophylactically (claim 5). Accordingly, the instantly claimed effects of such administration (*i.e.*, reducing the likelihood of incurring or developing estrogen-dependent breast cancer) would inherently result from administration of 60 mg/day of raloxifene hydrochloride to a post-menopausal woman having osteoporosis as claimed in the '847 patent.

Regarding "administration" as recited in the '847 patent claims, the specification of the '847 is used as a dictionary to define such administration. In this regard, the inventors teach that the term of period of time of administration to a human will be at least 6 months, normally at least one year, and preferably on a continual basis (col. 8, lines 24-30). The inventors further teach oral administration as recited in the instant claims (col. 7, lines 61-64).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Primary Examiner, Art Unit 1614

May 4, 2010